K050307

FEB 28 2005

Section 2

510(k) Summary of Safety and Effectiveness

Submitter Information

Submitter:	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44080-2371 ph: (330) 425-1313 fax: (330) 425-1410
Contact:	Douglas J. Thistlethwaite
Date:	February 4, 2005

Device Name

Classification Name:	Coil, magnetic resonance, specialty
Classification Number:	90MOS
Trade/Proprietary Name:	AIRIS Elite Rapid Body Coil
Predicate Device(s):	AIRIS Elite (K032232)

Device Intended Use

The MR system is an imaging device and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The body coil is a receive-only device that detects the MR signal used to produce transverse, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the body. The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

The indications for use are as follows:

Magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA) of the musculoskeletal structures, soft tissue and vascular structures within the anatomic regions from the chest to the pelvic region.

Device Description

Function

The AIRIS Elite Body Coil (hereby referred to as body coil) is a receive only RF phased array coil, used for obtaining diagnostic images of the abdominal region, in an open Magnetic Resonance Imaging (MRI) system.

Scientific Concepts

Magnetic Resonance Imaging (MRI) is based on the fact that certain atomic nuclei have electromagnetic properties that cause them to act as small spinning bar magnets. The most ubiquitous of these nuclei is hydrogen, which makes it the primary nuclei currently used in magnetic resonance imaging. When placed in a static magnetic field, these nuclei assume a net orientation or alignment with the magnetic field, referred to as a net magnetization vector. The introduction of a short burst of radiofrequency (RF) excitation of a wavelength specific to the magnetic field strength and to the atomic nuclei under consideration can cause a re-orientation of the net magnetization vector. When the RF excitation is removed, the protons relax and return to their original vector. The rate of relaxation is exponential and varies with the character of the proton and its adjacent molecular environment. This re-orientation process is characterized by two exponential relaxation times, called T1 and T2.

A RF emission or echo that can be measured accompanies these relaxation events. The receive coil detects these emissions which are used to develop a representation of the relaxation events in a three dimensional matrix. Spatial localization is encoded into the echoes by varying the RF excitation, applying appropriate magnetic field gradients in the x, y, and z directions, and changing the direction and strength of these gradients. Images depicting the spatial distribution of the NMR characteristics can be reconstructed by using image processing techniques similar to those used in computed tomography.

Physical and Performance Characteristics

The body coil consists two mechanical sections: a rigid removable upper section and a base, which is positioned above and below the patient abdomen respectively. The upper section can be connected to the base by the electrical pins. There is a latch on the upper section. The coil consists of four coil elements: a two-turn solenoid, an anterior saddle, a posterior saddle and an anti-turn loop. All the elements are enclosed in a rigid plastic housing. The signal output of each element is independently processed by the system to enhance performance.

Device Technological Characteristics

The technological characteristics of this device are similar to the predicate device. The device has four channels vs. two in the predicate device. Each channel output is independently processed.

Conclusions

It is the opinion of Hitachi Medical Systems America that the AIRIS Elite RAPID Body Coil is substantially equivalent to the body coil cleared with the AIRIS Elite MRI System. The technological characteristics and intended use are identical to the Predicate Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2005

Mr. Douglas Thistlewaite
Manager of Regulatory Affairs
Hitachi Medical Systems America
1959 Summit Commerce Park
TWINSBURG OH 44087-2371

Re: K050307
Trade/Device Name: AIRIS Elite Rapid Body Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: February 4, 2005
Received: February 8, 2005

Dear Mr. Thistlewaite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K050307

Device Name: AIRIS Elite Rapid Body Coil

Indications for Use:

Magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA) of the musculoskeletal structures, soft tissue and vascular structures within the anatomic regions from the chest to the pelvic region.

Prescription Use X AND/OR Over-the-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Lyman

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